

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

|                             |   |  |
|-----------------------------|---|--|
| In re Patent Application of | ) |  |
| Richard Gallo et al.        | ) |  |
| Application No.: 10/575,537 | ) | Group Art Unit: To Be Assigned                           |
| Filed: April 11, 2006       | ) | Examiner: To Be Assigned                                 |
| For: HUMAN CATHELICIDIN     | ) | Confirmation No.:  |
| ANTIMICROBIAL PEPTIDES      | ) |  |
|                             | ) | Certificate of Mailing                                   |
|                             | ) | I hereby certify that this paper is being deposited with |
|                             | ) | the United States Postal Service via Express Mail Post   |
|                             | ) | Office to Addressee under 37 C.F.R. §1.10 on May 3,      |
|                             | ) | 2006 in an envelope addressed to Mail Stop PCT,          |
|                             | ) | Commissioner for Patents, P.O. Box 1450, Alexandria,     |
|                             | ) | VA 22313-1450.   |
|                             | ) | By: _____  |
|                             | ) | Kim A. Cabello   |

**FIRST INFORMATION DISCLOSURE STATEMENT**

MAIL STOP PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, the accompanying information is being submitted in accordance with 37 C.F.R. §§ 1.97 and 1.98.

Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is enclosed. However, copies of the listed U.S. patents and U.S. patent application publications are not enclosed since it is no longer required according to the July 11, 2003 waiver of the requirement for copies of cited U.S. patents and U.S. patent application publications in national patent applications filed after June 30, 2003 and international applications entering the national stage under 35 U.S.C. § 371 after June 30, 2003.

The documents are being submitted within three (3) months of the filing or entry of the national stage of this application or before the first Office Action on the merits, whichever is later. Since these documents are being filed within the time period set forth in 37 C.F.R. § 1.97(b), no fee or statement is required.

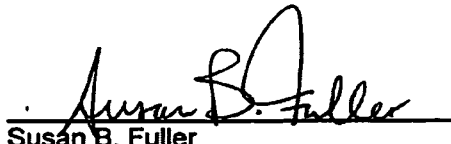
To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned.

Respectfully submitted,

BUCHANAN INGERSOLL PC

Date May 3, 2006

By:

  
Susan B. Fuller

Registration No. 51,979

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(858) 509-7300

**Buchanan Ingersoll PC**  
ATTORNEYS

Including attorneys from Burns Doane Swecker & Mathis

# **FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

**Complete if Known**

|  |                               |                |
|--|-------------------------------|----------------|
| <b>Sheet</b> <b>1</b> <b>of</b> <b>3</b> | <b>Application Number</b>     | 10/575,537     |
|  | <b>Filing Date</b>            | April 11, 2006 |
|  | <b>First Named Inventor</b>   | Gallo et al.   |
|  | <b>Examiner Name</b>          |                |
|  | <b>Attorney Docket Number</b> | 1034123-000219 |

**U.S. PATENT DOCUMENTS**

| Examiner Initials | Document Number | Kind Code (if known) | Name of Patentee or Applicant of Cited Document | Issue/Publication Date (MM-DD-YYYY) |
|-------------------|-----------------|----------------------|---|-------------------------------------|
|                   | 4,482,680       |                      | Sheldon   | 11-13-1984                          |
|                   | 5,618,675       |                      | Larrick   | 04/08/1997                          |
|                   | 6,040,291       |                      | Hirata  | 03/21/2000                          |
|                   | 2003/0022829    | A1                   | Maury   | 01/30/2003                          |
|                   |                 |                      |   |                                     |
|                   |                 |                      |   |                                     |
|                   |                 |                      |   |                                     |
|                   |                 |                      |   |                                     |
|                   |                 |                      |   |                                     |
|                   |                 |                      |   |                                     |
|                   |                 |                      |   |                                     |
|                   |                 |                      |   |                                     |
|                   |                 |                      |   |                                     |
|                   |                 |                      |   |                                     |

**FOREIGN PATENT DOCUMENTS**

| Examiner Initials | Document Number | Kind Code (if known) | Country | Date of Publication (MM-DD-YYYY) | STATUS      |                     |         |            |               |      |          |
|-------------------|-----------------|----------------------|---------|----------------------------------|-------------|---------------------|---------|------------|---------------|------|----------|
|                   |                 |                      |         |                                  | Translation | Partial Translation | Summary | Eng. Lang. | Search Report | IPER | Abstract |
|                   | WO 02/13857     |                      | WIPO    |                                  |             |                     |         |            |               |      |          |
|                   | WO 02/060468    | A2                   | WIPO    | 08/08/2002                       |             |                     |         |            |               |      |          |
|                   | 1 358 888       | A1                   | EP      | 11-05-2003                       |             |                     |         |            |               |      |          |
|                   |                 |                      |         |                                  |             |                     |         |            |               |      |          |
|                   |                 |                      |         |                                  |             |                     |         |            |               |      |          |
|                   |                 |                      |         |                                  |             |                     |         |            |               |      |          |
|                   |                 |                      |         |                                  |             |                     |         |            |               |      |          |
|                   |                 |                      |         |                                  |             |                     |         |            |               |      |          |
|                   |                 |                      |         |                                  |             |                     |         |            |               |      |          |
|                   |                 |                      |         |                                  |             |                     |         |            |               |      |          |
|                   |                 |                      |         |                                  |             |                     |         |            |               |      |          |

**NON-PATENT LITERATURE DOCUMENTS**

| Examiner Initials  | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. |
|--------------------|---|
|                    | Benincasa, Monica et al., "In vitro and in vivo antimicrobial activity of two alpha-helical cathelicidin peptides and of their synthetic analogs," Peptides, Vol. 24, No. 11, pp. 1723-1731, November 2003.   |
|                    | Brasel, Kenneth et al., Hematologic Effects on flt3 Ligand in Vivo in Mice, Blood, Vol. 88, No. 6, pp. 2004-2012, 1996.   |
|                    | Clinical and Experimental Dermatology Vol. 21, No. 3, pp.185, May 1996.   |
|                    | Gallo, Richard L. et al., "Identification of CRAMP, a cathelin-related antimicrobial peptide expressed in the embryonic and adult mouse," J. Biol. Chem., Vol. 272, No. 20, pp. 13088-93, May 16, 1997.   |
|                    | Gennaro, Renato et al., "Pro-rich antimicrobial peptides from animals: structure, biological functions and mechanism of action," Current Pharmaceutical Design. Vol. 8, No. 9, pp. 763-78, 2002.  |
|                    | Gennaro Renato et al., "Structural features and biological activities of the cathelicidin-derived antimicrobial peptides," Biopolymers, Vol. 55, No. 1, pp. 31-49, 2000.  |
| Examiner Signature | Date Considered   |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.  
CA 103254.1

# **FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

|       |   |    |   |                        |                |
|-------|---|----|---|------------------------|----------------|
| Sheet | 2 | of | 3 | Application Number     | 10/575,537     |
|       |   |    |   | Filing Date            | April 11, 2006 |
|       |   |    |   | First Named Inventor   | Gallo et al.   |
|       |   |    |   | Examiner Name          |                |
|       |   |    |   | Attorney Docket Number | 1034123-000219 |

## **NON-PATENT LITERATURE DOCUMENTS**

| Examiner Initials | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.     |
|-------------------|---|
|                   | Gennaro, Renato et al., "Biological characterization of a novel mammalian antimicrobial peptide," Biochimica et Biophysica Acta, Vol. 1425, No. 2, pp. 361-8, October 23, 1998.   |
|                   | Ha, Jong-Myung et al., "Synthesis and Antibiotic Activities of CRAMP, a Cathelin-related Antimicrobial Peptide and Its Fragments," Bull. Korean Chem. Soc., Vol. 20, No. 9, pp. 1073-1077, 1999.  |
|                   | Howell, Michael D. et al., "Selective Killing of Vaccinia Virus by LL-37: Implications for Eczema Vaccinatum," Journal of Immunology, Vol. 172, pp. 1763-1767, 2004.  |
|                   | Johnson, B.Connor, "Posttranslational Covalent Modification of Proteins," Academic Press, NY, pp. 1-12 1983.  |
|                   | Kaufman, Randal et al., "Synthesis, Processing, and Secretion of Recombinant Human Factor VIII Expressed in Mammalian Cells," Journal of Biological Chemistry Vol. 263, No. 13, pp. 6352-6362, 1988.  |
|                   | Kaufman, Randal, "Selection and Coamplification of Heterologous Genes in Mammalian Cells" Methods In Enzymology, Vol. 185 pp. 527-566, 1990.  |
|                   | McKinnon, P et al., "Expression, purification and characterization of secreted recombinant human insulin-like growth factor -I (IGF-I) and the potent variant des (1-3) IGF-I in Chinese hamster ovary cells" Journal Molecular Endocrinology 6, pp. 231-239, 1991. |
|                   | Merrifield, R.B., "Solid Phase Peptide Synthesis" Journal. Am. Chem. Soc., Vol.85, pp. 2149, 1962.  |
|                   | Ong, Peck et al., "Endogenous Antimicrobial Peptides And Skin Infections In Atopic Dermatitis," New England Journal of Medicine, Vol. 347, No. 15, pp. 1151-1160, October 10, 2002.   |
|                   | Rattan, Suresh I. et al., "Protein Synthesis, Posttranslational Modifications, and Aging," Annals of the N.Y. Academy of Science, Vol. 663, pp.48-62 (1992).  |
|                   | Sanchez et al., "Overexpression and structural study of the cathelicidin motif of the protegrin-3 precursor," Biochemistry, Vol. 41, No. 1, pp. 21-30, January 8, 2002.   |
|                   | Scott, Jamie et al., "Searching for Peptide Ligands with an Epitope Library," Science Voll. 249, pp.386-390 (1990).   |
|                   | Seifter, Sam et al., "Analysis for Protein Modifications and Nonprotein Cofactors," Methods of Enzymology, Vol. 182, pp. 626-646, 1990.   |
|                   | Skerlavaj, Barbara et al., "Structural and functional analysis of horse cathelicidin peptides," Antimicrobial Agents Chemotherapy., Vol. 45, No. 3, pp. 715-22, March 2001.   |
|                   | Smeianov, Vladimir et al. "Activity of cecropin P1 and FA-LL-37 Against urogenital microflora" Microbes and Infection, Vol. 2, pp. 773-777, 2000.   |
|                   | Smith, George, et al., "Libraries of Peptides and Proteins Displayed on Filamentous Phage," Methods Enzymology, Vol. 217, pp. 228-257, 1993.  |
|                   | Stewart, John, et al., "Solid Phase Peptides Synthesis," W.H. Freeman and Copmany, San Francisco, 1969, pp. 27-62.  |
|                   | Tjabringa, G. Sandra et al., "The Antimicrobial Peptide LL-37 Activates Innate Immunity at the Airway Epithelial Surface by Transactivation of the Epidermal Growth Factor Receptor," Journal of Immunology, Vol. 171, pp. 6690-6696, 2003.                         |
|                   | Urlaub, Gail et al., "Isolation of Chinese Hamster cell mutants deficient in dihydrofolate reductase activity," Proc Natl Acad Sci USA, Vol. 77, pp. 4216-4220, 1980.   |
|                   | Wood, Clive et al., "High Level Synthesis Of Immunoglobulins In Chinese Hamster Ovary Cells," The Journal of Immunology, Vo. 145, pp.3011-3016, 1990.   |
|                   | Zaiou, Mohamed et al., "Antimicrobial and Protease Inhibitory Functions of the Human Cathelicidin (hCAP18/LL-37) Prosequence," The Society for investigative Dermatology, Vol. 120, No. 5, pp. 810-816, May 2003.   |
|                   | Zanetti, Margherita et al., "Cathelicidin peptides as candidates for a novel class of antimicrobials," Current Pharmaceutical Design, Vol. 8, No. 9, pp. 779-93, 2002.  |
|                   | Zanetti, Margherita et al., "Structure and biology of cathelicidins," Adv. Exp. Med. Biol., Vol. 479, pp. 203-218, 2000.  |

|                    |                 |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

# **FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

**Complete if Known**

|  |                             |                |
|--|-----------------------------|----------------|
| <b>Sheet</b> <b>3</b> <b>of</b> <b>3</b> | <b>Application Number</b>   | 10/575,537     |
|  | <b>Filing Date</b>          | April 11, 2006 |
|  | <b>First Named Inventor</b> | Gallo et al.   |
|  | <b>Examiner Name</b>        |                |
| <b>Attorney Docket Number</b>            |                             | 1034123-000219 |

**NON-PATENT LITERATURE DOCUMENTS**

| Examiner<br>Initials | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. |
|----------------------|---|
|                      | Zanetti et al., "The cathelcidin family of antimicrobial peptide precursors: a component of the oxygen-independent defense mechanisms of neutrophils," Annals N. Y. Academy of Sciences, Vol. 832, pp. 147-62, December 15, 1997.                               |
|                      | Zanetti et al. "Cathelcidin Peptides as Candidates for a Novel Class of Antimicrobials" Current Pharmaceutical Design, Vol. 8, No. 9, pp 779-793, 2002  |

|                               |                            |
|-------------------------------|----------------------------|
| <b>Examiner<br/>Signature</b> | <b>Date<br/>Considered</b> |
|-------------------------------|----------------------------|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.